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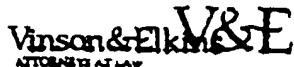
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5 MAY -6 P1:59

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## FACSIMILE TRANSMITTAL PAGE

DATE: May 6, 2003

Glenn A. Ballard, Jr.  
Bracewell & Patterson

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PHONE: 713.223.2900

TO: Marc Labgold  
Kevin M. Bell  
Paton Boggs (VA)

FAX: 703.744.8001

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TO: Richard J. Oparil  
Paton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 14 (including this transmittal page) CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/06/03 letter further responding to 04/14/03 Oparil letter.

Hard Copy Follows  Yes  No

### CONFIDENTIALITY NOTICE:

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May 6, 2003

*By Fax*

Mr. Richard J. Oparil  
Patton Boggs L.L.P.  
2550 M Street NW  
Washington, DC 20037

Re: *Baylor College of Medicine, et al. v. Clonitech Laboratories, Inc.*;  
Cause No. 2001-61352

Dear Richard:

I am further responding to your April 14 letter. Earlier I wrote regarding the Ruobo Zhang exhibits. As to the '808 continuations, we will be producing the non-privileged documents on this issue. In the meantime, I am providing the accompanying preliminary amendment and notice of allowance from the PTO.

Very truly yours,



David P. Blanke

attachment

c: Glenn A. Ballard, Jr. (by fax; w/att.)  
Kevin Bell (by fax; w/att.)  
Tracey B. Davies [Firm; w/o att.]  
M. Michelle Muller [Firm; w/o att.]  
Jason M. Powers [Firm; w/o att.]

MAY 06 2003 12:50 PM FR

SON & ELKINS 512 542 8612

#95382#91202457 P.03-14



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT PAPER

47

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

-See attached-

Notice of Allowability	Application No. 09/122,384	Applicant(s) ELLEDGE ET AL An Unis	
	Examiner James S. Ketter	1636	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address—**  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. THIS  
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the Initiative  
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to the amendment of 10/3/02 and the IDS of 3/4/03.
2.  The allowed claim(s) is/are 43-68.
3.  The drawings filed on 20 March 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some    c)  None    of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
(a)  The translation of the foreign language provisional application has been received.

6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

3.  CORRECTED DRAWINGS must be submitted.

(a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
 1)  hereto or 2)  to Paper No. \_\_\_\_.

(b)  including changes required by the proposed drawing correction filed \_\_\_\_, which has been approved by the Examiner.

(c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

3.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

Notice of References Cited (PTO-892)  
 Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 Information Disclosure Statements (PTO-1449), Paper No. 70-932 2 yr.  
 Examiner's Comment Regarding Requirement for Deposit of Biological Material  
  
 Notice of Informal Patent Application (PTO-152)  
 Interview Summary (PTO-413), Paper No. \_\_\_\_\_  
 Examiner's Amendment/Comment  
 Examiner's Statement of Reasons for Allowance  
 Other \_\_\_\_\_

JAMES KETTER  
PRIMARY EXAMINER



**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE  
 Commissioner for Patents  
 Washington, D.C. 20231  
 FAX (703)746-4000

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, Advance order and notifications of maintenance fees will be mailed to the current correspondence address as indicated unless corrected before or directed otherwise in Block 1, (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

**CURRENT CORRESPONDENCE ADDRESS (Type or Print):** Legacy Suite #100, 1000 Fannin, Houston, TX 77002

3186 7500 04/22/2003

VINSON & ELKINS, L.L.P.  
 1001 FANNIN STREET  
 2300 FIRST CITY TOWER  
 HOUSTON, TX 77002-6760

**Note:** A certificate of mailing shall only be used for domestic mailing of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission:**  
 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmisioned to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/121,184	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340

**TITLE OF INVENTION:** RAPID SUBCLONING USING SITES-SPECIFIC RECOMBINATION

APPLN. TYPE PROVISIONAL	SMALL ENTITY NO	ISSUE FEE \$1300	PUBLICATION FEE 50	TOTAL FEE(S) DUE \$1300	DATE DUE 07/22/2003
EXAMINER KITTER, JAMES S	ART UNIT 1636	CLASS-SUBCLASS 435-000000			

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).  
 Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
 "Fee Address" indication (or "Fee Address" indication form PTO/SB/47; Rev 01-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

**3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

**PLEASE NOTE:** Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignee has  
 been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE  
 (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  corporation or other private group entity  government  
 4a. The following fee(s) are attached:

Issue Fee  
 Publication Fee  
 Advance Order - # of Copies \_\_\_\_\_  
 4b. Payment of Fee(s):  
 A check in the amount of the fee(s) is enclosed.  
 Payment by credit card. Form PTO-2018 is attached.  
 The Commissioner is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid fees due to the application identified above.

(Authorized Signature) (Date)

**NOTE:** The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party to whom it is issued as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to be had by the USPTO to process an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1996	STEPHEN J. ELLEDGE	BAY1364-010CJP	6340
21386	750	04/22/2003		EXAMINER
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 04/22/2003				

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

MAY 06 2003 12:51 PM FR

ON &amp; ELKINS 512 542 8612

95302891202457 P.08-14



## UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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WASHINGTON, D.C. 20591  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,314	07/24/1998	STEPHEN J. ELEDGE	BAY1364-010CIP	4340
31314	04/22/2003			EXAMINER
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760 UNITED STATES			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1036	
DATE MAILED: 04/22/2003				

## Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/maju/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

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95302491202457 P.09-14

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V&E

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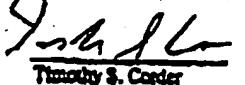
Timothy S. Corder  
Direct Dial 512-542-8446  
Direct Fax 512-236-3377  
tcorder@velaw.com

October 3, 2002

CERTIFICATE OF FACSIMILE

I certify that this correspondence is being transmitted on October 3, 2002, by facsimile to the Patent and Trademark Office in accordance with 37 C.F.R. § 1.8.

October 3, 2002  
Date

  
Timothy S. Corder

Assistant Commissioner for Patents  
Washington, D.C. 20231

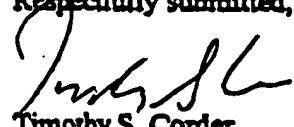
Re: U.S. Patent Application SN 09/122,384 "Rapid Subcloning Using Site-Specific Recombination," by Elledge et al.  
Attorney Docket No.: BAY136/4-010CIP/36000; Client Ref.: OTA # 97-27  
Confirmation No. 4340

Sir:

Enclosed for filing in the above-referenced patent application is a Preliminary Amendment for filing in the above-referenced patent application.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to appropriately deduct or credit the requisite amount from Vinson & Elkins L.L.P. deposit account No. 22-0365/BAY136/4-010CIP/36000.

Respectfully submitted,

  
Timothy S. Corder  
Reg. No. 38,414

9282:5588

Enclosure

311728\_1.DOC

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

For: Rapid Subcloning Using Site-Specific Recombination

Group Art Unit: 1636

Examiner: J. Ketter

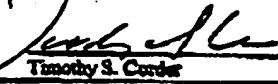
Att. Dkt. No.: BAY136/4-10CIP/36000

Confirmation No. 4340

CERTIFICATE OF FACSIMILE

I certify that this correspondence is being transmitted on October 3, 2002, by facsimile to the Patent and Trademark Office in accordance with 37 C.F.R. §1.8.

October 1, 2002

  
Timothy S. Carter

PRELIMINARY AMENDMENT

VIA FACSIMILE NO. 703-746-5155

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In advance of prosecution, the Examiner is requested to please amend the above-captioned application as follows:

AMENDMENT

A. In the Claims:

Please cancel all pending claims, i.e. claims 1-20, 26, 30-35, and 37-42, and enter the following new claims:

43. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide.

44. The composition of claim 43, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
45. The composition of claim 43, wherein the composition comprises an enzyme activity with a Cre recombinase efficiency of about 16.8% per microgram of protein.
46. An isolated nucleic acid molecule comprising a coding region wherein the coding region encodes a glutathione-S-transferase-Cre recombinase fusion polypeptide.
47. The nucleic acid molecule of claim 46, wherein the coding region comprises the nucleic acid sequence of SEQ ID NO:10.
48. The nucleic acid molecule of claim 46, wherein the isolated nucleic acid molecule is an expression vector.
49. The nucleic acid molecule of claim 46, wherein the coding region is operatively linked to a promoter effective to direct expression of a glutathione-S-transferase-Cre recombinase fusion polypeptide.
50. The nucleic acid molecule of claim 49, wherein the promoter is an inducible promoter.
51. The nucleic acid of claim 50, wherein the promoter is the lac promoter.
52. A host cell comprising the nucleic acid molecule of claim 46.
53. A host cell comprising the nucleic acid molecule of claim 49.
54. The host cell of claim 53, wherein the host cell expresses a Cre recombinase activity.

55. The host cell of claim 53, further defined as an *E. coli* cell.
56. A bacterial cell engineered to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
57. The bacterial cell of claim 56, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
58. A method of producing a glutathione-S-transferase-Cre-recombinase fusion polypeptide comprising:
  - obtaining an expression vector comprising a coding region encoding a glutathione-S-transferase-Cre-recombinase fusion polypeptide operatively linked to a promoter;
  - transforming or transfecting the vector into a cell; and
  - growing the cell under conditions effective to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
59. The method of claim 58, further comprising isolating the glutathione-S-transferase-Cre-recombinase fusion polypeptide.
60. The method of claim 59, wherein isolating the polypeptide comprises glutathione affinity chromatography.
61. A method of recombining nucleic acid segments, wherein each segment comprises a *lox* site specific recombinase site, the method comprising contacting the nucleic acid segments with a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
62. The method of claim 61, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.

63. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide and one or more nucleic acid molecules, wherein the nucleic acids comprise a site specific recombinase site.
64. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a lox recombination site upstream in a 5' to 3' orientation from an amino acid encoding region.
65. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a transcription regulatory element upstream in a 5' to 3' orientation of a lox recombinase site.
66. The composition of claim 64 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
67. The composition of claim 65 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
68. The composition of claim 64, wherein the amino acid encoding region is a member of a nucleic acid library.

## II. REMARKS

The claims in this preliminary amendment do not add new matter to the application and their entry is therefore respectfully requested. Support for the claims may be found throughout the Specification and at least in Example 3 found on page 47.

## IV. CONCLUSION

Applicants respectfully submit that the present application and all claims are in condition for immediate allowance and early notice to such effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help expedite prosecution of this application, the Examiner is invited to contact the undersigned representative at (512) 542-8446.

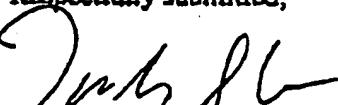
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ON & ELKINS 512 542 8612

95382891202457 P.14-14

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account No. 22-0365/BAY136/4-10CIP/36000.

Respectfully submitted,

  
Timothy S. Corder  
Reg. No. 38,414  
Agent for Applicant

Vinson & Elkins L.L.P.  
2300 First City Tower  
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Houston, Texas 77002-6760  
512/542-8446

Date: October 3, 2002